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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/078,113	02/19/2002	S. Christopher Bauer	126181-1013	4542
7590	11/26/2003			EXAMINER LANDSMAN, ROBERT S
Carol M. Nielsen GARDERE WYNNE SEWELL LLP Suite 3000 1601 Elm Street Dallas, TX 75201-4761			ART UNIT 1647	PAPER NUMBER 7
DATE MAILED: 11/26/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	10/078,113	BAUER ET AL.
	Examiner Robert Landsman	Art Unit 1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1)  Responsive to communication(s) filed on \_\_\_\_.
- 2a)  This action is FINAL.                            2b)  This action is non-final.
- 3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4)  Claim(s) 1 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5)  Claim(s) \_\_\_\_ is/are allowed.
- 6)  Claim(s) 1 is/are rejected.
- 7)  Claim(s) \_\_\_\_ is/are objected to.
- 8)  Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9)  The specification is objected to by the Examiner.
- 10)  The drawing(s) filed on \_\_\_\_ is/are: a)  accepted or b)  objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11)  The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. §§ 119 and 120

- 12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All    b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

- 13)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.  
a)  The translation of the foreign language provisional application has been received.
- 14)  Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). ____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____	6) <input checked="" type="checkbox"/> Other: "Continuity Information for 07/981044"

## DETAILED ACTION

### ***1. Formal Matters***

A. Claims 1-65 were pending. In the Preliminary Amendment filed 2/19/02, Applicants cancelled claims 2-65. Therefore, claim 1 is pending and is the subject of this Office Action.

### ***2. Specification***

A. The specification is objected to since there is no sequence identifier in Figure 3, or in the Brief Description.

### ***3. Double Patenting - Statutory***

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

A. Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of at least claim 1 of prior U.S. Patent No. 6,458,931. This is a double patenting rejection. Both claims recite the IL-3 mutant of SEQ ID NO:15.

### ***4. Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the

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conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

A. Claim 1 is rejected under the judicially created doctrine of double patenting over at least claim 1 of U. S. Patent No. 6,458,931 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: both the patent and application teach numerous variants of SEQ ID NO:15.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

**\* Both a statutory and non-statutory rejection are being made of record since, due to the complexity of the claims, it is not clear as to which rejection is proper. Therefore, these rejections will be maintained until Applicants' arguments are deemed persuasive.**

**\*\* Furthermore, due to the large number of co-pending and allowed cases claiming IL-3 mutants, all of which are complex, the Examiner requests that Applicants submit the claims which would be considered "double patenting" with the present invention. Due to the length of the claims, Applicants are invited to submit only the application serial numbers and claim numbers in lieu of submitting the claims. This would be preferred. However, if Applicants submit Terminal Disclaimers, then no submission of claims from other cases is necessary. A list of some potential applications are attached (see sheet entitled "Continuity Information for 07/981,044").**

##### **5. Claim Rejections - 35 USC § 112, second paragraph**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The following limitations were recited in previous US Patents which are parents of the instant case. However, these limitations are not recited in the current claims. Therefore, Applicants are requested to recite these limitations in the claims, or to provide an explanation as to why these limitations should not be included. It is believed that these limitations were required to overcome prior art and scope of enablement rejections:

- (a) with the proviso that no more than one of the amino acids at positions 63, 82, 87, 98, 112, and 121 are different from the corresponding amino acids in native human interleukin-3; and
- (b) wherein said modified human interleukin-3 (hIL-3) amino acid sequence has increased activity, relative to native human interleukin-3, in at least one assay selected from the group consisting of: AML cell proliferation, TF-1 cell proliferation and Methylcellulose assay; R.sub.2 is a hematopoietic growth factor; and L is a linker capable of linking R.sub.1 to R.sub.2; and (b) harvesting said cultured stem cells.
- (c) provided that the residues corresponding to positions 101 or 116 are not Ala or Val, respectively and wherein a polypeptide having only the sequence of said mutant human interleukin-3 polypeptide R.sub.1 has at least three times greater activity than native human interleukin-3, in at least one assay selected from the group consisting of: AML cell proliferation, TF-1 cell proliferation and Methylcellulose assay;

*Advisory information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman whose telephone number is (703) 306-3407. The examiner can normally be reached on Monday - Friday from 8:00 AM to 5:00 PM (Eastern time) and alternate Fridays from 8:00 AM to 5:00 PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Kunz, can be reached on (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4242. Fax draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert Landsman, Ph.D.  
Patent Examiner  
Group 1600  
November 25, 2003



ROBERT LANDSMAN  
PATENT EXAMINER